

HERBAL MEDICINES

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National
Toxicology
Program

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Medicinal herbs are some of our oldest medicines and their increasing use in recent years is evidence of a public interest in having alternatives to conventional medicine. Herbal medicines currently account for one of the fastest growing markets in U.S. pharmacies and constitute a multi-billion dollar industry. Market size is predicted to approximately double between 1997 and 2001. Although approximately 1500 botanicals are sold as dietary supplements or ethnic traditional medicines, herbal formulations are not subject to FDA premarket toxicity testing to assure their safety or efficacy.

In response to concerns regarding the use and efficacy of medicinal herbs and to recent nominations of these products for study by the NTP, a workshop on herbal medicines was organized to address research needs. This workshop was sponsored by the NTP in conjunction with the NIH Office of Dietary Supplements, the DHHS Office of Disease Prevention and Health Promotion, the FDA Office of Special Nutrition, and the Society for the Advancement of Women's Health Research and held 23-24 September 1998 in Raleigh, NC. Its objectives were to discuss the use, safety, and possible health-related problems associated with the use of medicinal herbs; identify how other countries evaluate and regulate medicinal herbs; establish the NTP's role in determining their long-term safety; and recommend areas for research. A broader objective of the meeting was the focus and coordination of U.S./international research efforts. Recommendations from the workshop include a call for more research, identification and standardization of product ingredients by industry, and increased consumer education through package inserts.

In follow-up to this workshop, the NTP staff is working with the NIH Office of Dietary Supplements, the FDA, the academic community, and others to further define and implement research that addresses deficiencies in our knowledge about herbal medicines and their potential toxicities. Several herbs and active or toxic ingredients found in some herbs have been nominated and selected for study by the NTP. Studies have been designed for many of these herbal products and will begin the coming year. These studies will focus on characterization of potential adverse health effects including reproductive toxicity, neurotoxicity, and immunotoxicity as well as those associated with acute high dose exposure and chronic exposure to lower doses. In addition, special attention will be given to the potential for herb/herb and herb/drug interactions and the responses of sensitive subpopulations (e.g. pregnant women, the young, the developing fetus, the elderly, etc). NTP studies include both traditional toxicological research and molecular mechanistic considerations. Comments from the public and others regarding NTP research in this area are welcome and should be forwarded to the NTP Liaison and Scientific Review Office.

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Herbs and Active or Toxic Ingredients for Study by the NTP

<i>Herb or Ingredient</i>	<i>Information</i>
Aloe Vera Gel	Seventh most widely used herb; used as both a dietary supplement and component of cosmetics. The gel has been used for centuries as a treatment for minor burns and is increasingly being used in products for internal consumption (e.g., "health" drinks).
Black Walnut Extract (BWE)	BWE is found in hair dye formulations and walnut oil stain. It is used both internally and externally as herbal remedy for a variety of conditions. Juglone is a major constituent of BWE.
Comfrey	Herb consumed in teas and as fresh leaves for salads; however, it contains pyrrolizidine alkaloids (e.g., symphatine), which are known to be toxic. Used externally as an anti-inflammatory agent in the treatment of bruises, sprains, and other external wounds.
<i>Echinacea purpurea</i> Extract	One of the most commonly used medicinal herb in the United States. Used as an immunostimulant to treat colds, sore throat, and flu.
<i>Ginkgo biloba</i> Extract	Among the five or six most frequently used medicinal herbs. Ginkgo fruits and seeds have been used medicinally for thousands of years. The extract of green-picked leaves has increasing popularity in the United States. <i>Ginkgo biloba</i> extract promotes vasodilatation and improved blood flow and appears beneficial, particularly for short-term memory loss, headache, and depression.
Ginseng and Giensenoside	Fourth most widely used medicinal herb; giensenosides are thought to be the active ingredients. Ginseng has used as a treatment for a variety of conditions: hypertension, diabetes, and depression, and been associated with various adverse health effects.
Goldenseal	Second or third most popular medicinal herb used in this country; traditionally used to treat wounds, digestive problems, and infections. Current uses include as a laxative, tonic, and diuretic.
Kava Kava	Reported to be the fifth most widely used medicinal herb, has psychoactive properties, and is sold as a calmative and antidepressant.
Milk Thistle Extract	Used to treat depression and several liver conditions including cirrhosis and hepatitis and to increase breast milk production.
Pulegone	A major terpenoid constituent of the herb, Pennyroyal, is found in lesser concentrations in other mints. Pennyroyal has been used as a carminative insect repellent, emmenagogue, and abortifacient. Pulegone has well-recognized toxicity to the liver, kidney, and central nervous system.
Thujone	Terpenoid found in a variety of herbs, including sage and tansy, and in high concentrations in wormwood. Suspected as the causative toxic agent associated with drinking absinthe, a liqueur flavored with wormwood extract